

REMARKS

The invention relates to kinase inhibitors and use of these kinase inhibitors to inhibit the phosphorylation activity of a signal transduction kinase.

Claims 33-37 are pending and under examination; claims 1-32 and 38-45 are withdrawn from consideration. New claim 46 has been added. Claim 33 has been amended to include the limitations of claims 34-37. Claims 34-37 have been cancelled. No new matter has been added as a result of this amendment.

Applicants wish to thank Examiner Yu and Examiner Caputa for the courtesy extended to their attorneys during a telephonic interview on July 30, 2003.

Rejection of Claims 33-37 under 35 U.S.C. § 112, first paragraph

Claims 33-37 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to meet the written description requirement.

The Office Action suggests that the specification fails to provide adequate written description for the phrase “a signal transduction kinase that binds to an RKIP family member,” and only describes two members of this genus of kinases. The Office Action states at page 3, lines 13-14, that “the specification provides evidence for two species, Raf-1 and MEK that binds to [a] RKIP family member.”

Claim 33 has been amended to recite a “signal transduction kinase that binds an RKIP family member selected from the group consisting of: Raf-1 and MEK”. Support for this limitation is found throughout the specification and at least in Examples 1, 4, 5 and 6.

Claims 34-37 have been cancelled.

Claim 33 is also rejected for allegedly failing to meet the written description requirement for the phrase “an agent that increases or inhibits the activity of a polypeptide comprising an RKIP motif.”

The Office Action states at page 6, line 22- page 7, line 11, that “[t]he claim is interpreted as drawn to a method using a **genus of agents** that increase or inhibit the activity of a polypeptide comprising an RKIP motif for the purpose stated in the preamble i.e., inhibiting the phosphorylation activity of a signal transduction kinase that binds said polypeptide” (emphasis in the original). The “rejection is based on the Office’s interpretation of ‘an agent that increase[s] activity of a polypeptide comprising an RKIP motif’ as agonists to said polypeptide, and ‘an agent that decrease activity of a polypeptide comprising an RKIP motif as antagonists to said polypeptide.’ The specification fails to teach structure, formula, or chemical name of any RKIP agonists and/or antagonists capable [of] accomplishing the purpose in [the] preamble of the claims, other than saying that screening such agonists and/or antagonists are possible using various art known assays...”

Claim 33 has been amended to claim “a method of inhibiting the phosphorylation activity of a signal transduction kinase that binds an RKIP family member, selected from the group consisting of Raf-1 and MEK, comprising the step of contacting said signal transduction kinase with an amount of a polypeptide comprising an RKIP motif, that inhibits the phosphorylation activity of said signal transduction kinase that binds an RKIP family member.”

Amended claim 33 recites a “polypeptide comprising an RKIP motif” and does not relate to a genus of agents that increase or inhibit the activity of a polypeptide comprising an RKIP motif. It is submitted that the specification discloses a polypeptide comprising an RKIP motif throughout the instant specification and, in particular, at Figure 1 and in example 4. An “RKIP motif” is defined at p. 8, line 20 through p. 9, line 9.

Finally, claims 33-37 are rejected for allegedly failing to meet the written description requirement. for the newly added phrase “agent that increase or inhibits the activity of a polypeptide comprising an RKIP motif” in independent claim 33 (see Office Action, page 8, lines

5-9). The Office action further states that "RKIP protein modulates its own activity because claim 35 says 'the agent' in the base claim is a RKIP protein."

Amended claim 33 claims "a polypeptide comprising an RKIP motif" and no longer claims "an agent that increases or inhibits the activity of a polypeptide comprising an RKIP motif", thereby rendering this rejection moot.

In view of all of the above, amended claim 33 meets the legal requirement for written description (dependent claims 34-37 have been cancelled). Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

Rejection of claims 33, 34, 36 and 37 Under 35 U.S.C. §102

Claims 33, 34, 36 and 37 remain rejected under 35 U.S.C. §102(b) for alleged lack of novelty in view of Jelinek et al. (March 1996, Molecular and Cellular Biology, Vol. 16, pp. 1027-1034).

The Office Action states at p. 4, line 22 through p. 5, line 2, that "[t]he prior art teaches an agent that suppresses the phosphorylation activity of raf-1 (a signal transduction kinase) by contacting said kinase with an agent (i.e., PTP-1B)."

For a determination of anticipation to be proper, the prior art reference must disclose each and every limitation of the claim. *Atlas Powder Company et al. v. IRECO, Incorporated et al.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

Claim 33 has been amended to recite "a method of inhibiting the phosphorylation activity of a signal transduction kinase that binds an RKIP family member, selected from the group consisting of Raf-1 and MEK, comprising the step of contacting said signal transduction kinase with an amount of a polypeptide comprising an RKIP motif, that inhibits the phosphorylation activity of said signal transduction kinase that binds an RKIP family member."

Claims 34-37 have been cancelled.

The Jelinek et al. reference teaches inactivation of Ras by the protein tyrosine phosphatase PTB-1B; it does not teach that PTB-1B is a “polypeptide comprising an RKIP motif”, as recited in claim 33 and as defined in the instant application.

In view of the amendment to claim 33, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) rejection in view of the Jelinek et al. reference.

Rejection of claims 33 and 36 Under 35 U.S.C. §102(e)

Claims 33 and 36 remain rejected under 35 U.S.C. §102(e) for alleged lack of novelty in view of U.S. 6,187,799.

The Office Action states at p. 6, lines 7-11, that “[t]he Office maintains that the agent of the prior art meets the limitation of [the] instant claims since the agents accomplish the preamble of the instant claims by the active steps of the instant invention and the agent increase[s] the activity of RKIP protein (i.e., suppress Raf-1 mediated signaling).”

For a determination of anticipation to be proper, the prior art reference must disclose each and every limitation of the claim. *Atlas Powder Company et al. v. IRECO, Incorporated et al.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

Claim 33 has been amended to claim: “a method of inhibiting the phosphorylation activity of a signal transduction kinase that binds an RKIP family member, selected from the group consisting of Raf-1 and MEK, comprising the step of contacting said signal transduction kinase with an amount of a polypeptide comprising an RKIP motif, that inhibits the phosphorylation activity of said signal transduction kinase that binds an RKIP family member.”

Claims 34-37 have been cancelled.

The U.S. 6,187,799 reference teaches methods of treating tumors mediated by raf kinase using substituted urea compounds; it does not teach that any of the disclosed urea compounds are

a "polypeptide comprising an RKIP motif", as recited in claim 33.

In view of the amendment to claim 33 and the cancellation of claim 36, Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. §102(e) rejection of claims 33 and 36 in view of the U.S. 6,187,799 reference.

Rejection of Claims 33-37 under 35 U.S.C. § 112, second paragraph

Claims 33-37 are rejected under 35 U.S.C. § 112, first paragraph, for alleged indefiniteness.

The Office Action states at page 6, lines 16-17, "[c]laim 33 recites the limitation 'the activity' in line 3. There is insufficient antecedent basis for this limitation in the claim." In view of the amendment to claim 33, wherein the recitation of the phrase, "the activity" has been deleted from line 3, this rejection is rendered moot.

Claim 33 has been amended to recite a "signal transduction kinase that binds an RKIP family member wherein said signal transduction kinase is Raf-1 or MEK." Claims 34-37 have been cancelled.

In view of all of the above, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. §112, first paragraph rejection of claims 33-37.

